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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,545	02/10/2004	Ran Kornowski	MEDIV2010-5	3121
28213	7590	06/05/2007	EXAMINER	
DLA PIPER US LLP			GUZO, DAVID .	
4365 EXECUTIVE DRIVE			ART UNIT	
SUITE 1100			PAPER NUMBER	
SAN DIEGO, CA 92121-2133			1636	
			MAIL DATE	DELIVERY MODE
			06/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/776,545	Applicant(s) KORNOWSKI ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7,11,36,45,46,53,62,63,70,79 and 80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,11,36,45,46,53,62,63,70,79 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/9/04;4/12/04;1/17/06;2/21/06;8/26/04.

### **Detailed Action**

#### **Election/Restriction**

Applicant's election of Group II, Claims 1, 7, 10, 11, 36, 45, 46, 53, 62, 63, 70, 79 and 80 and the species MCP-1 in the reply filed on 5/19/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### **Obviousness Type Double Patenting Rejections**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7, 11, 36, 45, 46, 53, 62, 63, 70, 79 and 80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

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over claims 17, 19, 24, 25, 29-32, 34 and 47-49 of copending Application No.

10/618,183 (hereafter the '183 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for enhancing collateral blood vessel formation in heart tissue, said method comprising administering to ischemic heart muscle (i.e. a site of impaired blood flow) autologous bone marrow cells which have been transfected with vectors (i.e. adenoviral vectors) encoding a gene expressing an angiogenic factor such as HIF-1, MCP-1, GM-CSF, etc.). The instant claims are broader (i.e. generic) to the claims in the '183 application in that they recite generically administering the cells to the heart tissue (rather than injecting them as per the '183 application), the instant claims recite administering of bone marrow aspirates rather than a aspirate subset referred to as early attaching cells or stromal cells, etc. The preambles of claims 36, 53 and 70 recite improving the electrical conductivity of the heart, enhancing myocardial function and improving atrial or ventricular function, respectively; however, the method step involved is the same as that recited in the '183 application and the preambles of the instant claims are achieved by the same outcome as recited in the '183 application (i.e. enhancing collateral blood vessel formation). The claims in the '183 application represent species of the instant invention and would anticipate the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 36, 53 and 70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 18 of U.S. Patent No. 7,097,832 (hereafter the '832 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for enhancing collateral blood vessel formation in heart tissue, said method comprising administering to ischemic heart muscle autologous bone marrow aspirate. The preambles of claims 36, 53 and 70 recite improving the electrical conductivity of the heart, enhancing myocardial function and improving atrial or ventricular function, respectively; however, the method step involved is the same as that recited in the '832 patent (administering autologous bone marrow aspirates to the heart) and the preambles of the instant claims are achieved by the same outcome as recited in the '832 patent (i.e. enhancing collateral blood vessel formation). The instant claims are therefore obvious over the claims in the '832 patent.

#### **Oath/Declaration**

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Non-initialed alterations have been made to the Residence and Post Office Address of Inventor Martin B. Leon.

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The closest prior art is represented by Folkman, Circulation, 1998, Vol. 97, pp. 1108-1110. Folkman and other prior art teach therapeutic angiogenesis in ischemic limbs wherein vectors comprising genes encoding angiogenic proteins (i.e. VEGF) are delivered to the ischemic sites and the gene is expressed resulting in induced collateral neovascularization.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
May 25, 2007

  
DAVID GUZO  
PRIMARY EXAMINER